

13

The mixed granulation then was compressed into tablets using a rotary compression machine. The core tablets were film coated with an aqueous suspension of the appropriate color mixture in a coating pan (e.g., Accela Cota). The coated tablets can be lightly dusted with talc to improve tablet handling characteristics.

The tablets are filled into plastic containers (30 tablets/container) and accompanied by package insert describing the safety and efficacy of the formulation.

EXAMPLE 5

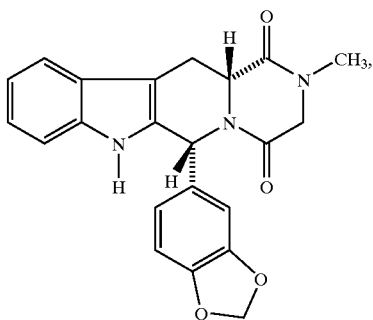
By analogous procedures, the following formula was used to prepare the finished dosage form of a tablet providing 5.0 mg and 20 mg of compound (I).

Ingredient	Quantity (mg)	Quantity (mg)
<u>Granulation</u>		
Compound (I) (Lot 1, d90 of 4)	5.00	20.00
Lactose Monohydrate	109.66	210.19
Lactose Monohydrate (Spray Dried)	17.50	35.00
Hydroxypropylcellulose	2.80	5.60
Croscarmellose Sodium	6.30	12.60
Hydroxypropylcellulose (EF)	1.22	2.45
Sodium Lauryl Sulfate	0.49	0.98
<u>Outside Powders</u>		
Microcrystalline Cellulose (Granular-102)	26.25	52.50
Croscarmellose Sodium	4.90	9.80
Magnesium Stearate (Vegetable)	0.88	0.88
Total	175 mg	350 mg

The principles, preferred embodiments, and modes of operation of the present invention have been described in the foregoing specification. The invention that is intended to be protected herein, however, is not construed to be limited to the particular forms disclosed, because they are to be regarded as illustrative rather than restrictive. Variations and changes may be made by those skilled in the art without departing from the spirit of the invention.

What is claimed is:

1. A free drug particulate form of a compound having a formula



or pharmaceutically acceptable salts and solvates thereof, comprising particles of the compound wherein at least 90% of the particles have a particle size of less than about 40 microns.

14

2. The free drug particulate form of claim 1 wherein at least 90% of the particles have a particle size of less than about 25 microns.

3. The free drug particulate form of claim 1 wherein at least 90% of the particles have a particle size of less than about 15 microns.

4. The free drug particulate form of claim 1 wherein at least 90% of the particles have a particle size of less than about 10 microns.

5. A pharmaceutical solid composition comprising the free drug particulate form as in any one of claims 1-4 and one or more pharmaceutically-acceptable carriers, diluents, or excipients.

6. A method of treating sexual dysfunction in a patient in need thereof, which comprises administering to the patient a therapeutically effective amount of a solid composition comprising the free drug particulate form as in any one of claims 1-4 and one or more pharmaceutically-acceptable carriers, diluents, or excipients.

7. The method of claim 6 wherein the sexual dysfunction is male erectile dysfunction.

8. The method of claim 6 wherein the sexual dysfunction is female sexual arousal disorder.

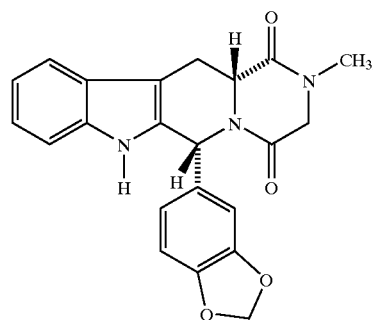
9. A method of manufacturing the free drug particulate form of claim 1 comprising:

(a) providing a solid, free form of the compound, and

(b) comminuting the solid free form of the compound to provide particles of the compound wherein at least 90% of the particles have a particle size of less than about 40 microns.

10. The method of claim 9 further comprising the step of admixing the particles of step (b) with one or more pharmaceutically-acceptable carriers, diluents, or excipients.

11. A pharmaceutical solid composition prepared by admixing particles of a compound having a formula



or a pharmaceutically acceptable salt or solvate thereof, with one or more pharmaceutically acceptable carrier, diluent, or excipient, wherein the particles of the compound have a d90=40 or less.

* * * * *